

Food and Drug Administration, HHS

§ 178.3295

§ 178.3295 Clarifying agents for polymers.

Clarifying agents may be safely used in polymers that are articles or compo-

nents of articles intended for use in contact with food, subject to the provisions of this section:

Substances	Limitations
Aluminum, hydroxybis[2,4,8,10-tetrakis(1,1-dimethylethyl)-6-hydroxy-12H-dibenzo[d,g][1,3,2]dioxaphosphocin 6-oxidato]- (CAS Reg. No. 151841-65-5).	For use only as a clarifying agent at levels not to exceed 0.25 percent by weight of polypropylene and polypropylene copolymers complying with § 177.1520(c) of this chapter, items 1.1, 3.1, or 3.2. The finished polymers contact food only of types I, II, IV-B, VI-B, VII-B, and VIII as identified in Table 1 of § 176.170(c) of this chapter, under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter or foods only of types III, IV-A, V, VI-A, VI-C, VII-A, and IX as identified in Table 1 of § 176.170(c) of this chapter, under conditions of use C through G described in Table 2 of § 176.170(c) of this chapter.
Bis(<i>p</i> -ethylbenzylidene) sorbitol (CAS Reg. No. 79072-96-1) ...	For use only as a clarifying agent at a level not to exceed 0.35 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1a, 1.1b, 3.1a, 3.2a, or 3.2b, where the copolymers complying with items 3.1a, 3.2a, or 3.2b contain not less than 85 weight percent of polymer units derived from propylene.
Di(<i>p</i> -tolylidene) sorbitol (CAS Reg. No. 54686-97-4)	For use only as a clarifying agent at a level not to exceed 0.32 percent by weight in propylene homopolymer complying with § 177.1520(c) of this chapter, item 1.1, and in olefin copolymers complying with § 177.1520(c) of this chapter, item 3.1 (containing at least 85 weight percent of polymer units derived from propylene), in contact with all food types under conditions of use C through G described in table 2 of § 176.170(c) of this chapter.
Dibenzylidene sorbitol (CAS Reg. No. 32647-67-9) formed by the condensation of two moles of benzaldehyde with one mole of sorbitol, such that the final product has a minimum content of 95 percent dibenzylidene sorbitol.	For use only as a clarifying agent for olefin polymers complying with § 177.1520(c) 1.1, 3.1, and 3.2 of this chapter under conditions of use C, D, E, F, and G, described in table 2 of § 176.170(c) of this chapter at a level not exceeding 0.25 percent by weight of the polymer.
Dimethyldibenzylidene sorbitol (CAS Reg. No. 135861-56-2)	For use only as a clarifying agent at a level not to exceed 0.4 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 3.1, and 3.2, where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from polypropylene. The finished polymers shall be used in contact with food under conditions of use A through H described in table 2 of § 176.170(c) of this chapter.
Polyvinylcyclohexane (CAS Reg. No. 25498-06-0)	For use only as a clarifying agent for polypropylene complying with § 177.1520(c) of this chapter, item 1.1., and in propylene containing copolymers complying with § 177.1520(c) of this chapter, items 3.1 and 3.2, at a level not exceeding 0.1 percent by weight of the polyolefin.
Sodium di(<i>p</i> - <i>tert</i> -butylphenyl)phosphate (CAS Reg. No. 10491-31-3).	For use only as a clarifying agent at a level not exceeding 0.35 parts per hundred of the resin in olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from propylene).

Substances	Limitations
Sodium 2,2'-methylenebis(4,6-di- <i>tert</i> -butylphenyl)phosphate (CAS Reg. No. 85209–91–2).	<p>For use only:</p> <ol style="list-style-type: none"> 1. As a clarifying agent at a level not exceeding 0.30 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 3.1, or 3.2 (where the copolymers complying with items 3.1 and 3.2 contain not less than 85 weight percent of polymer units derived from polypropylene). The finished polymers contact foods only of types I, II, IV-B, VI-B, VII-B, and VIII as identified in table 1 of § 176.170(c) of this chapter and limited to conditions of use B through H, described in table 2 of § 176.170(c), or foods of all types, limited to conditions of use C through H described in table 2 of § 176.170(c). 2. As a clarifying agent at levels not exceeding 0.10 percent by weight of polypropylene complying with § 177.1520(c) of this chapter, items 1.1(a) or 1.1(b) and of olefin polymers complying with § 177.1520(c) of this chapter, items 3.1(a), 3.1(b), 3.1(c), 3.2(a), or 3.2(b) (where the copolymers contain not less than 85 weight percent of the polymer units derived from polypropylene.) The finished polymers shall be used in contact with foods only under conditions of use A through H described in Table 2 of § 176.170(c) of this chapter. 3. As a clarifying agent at a level not exceeding 0.30 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, item 2.2, where the finished polymer contacts food only of types I, II, IV-B, VI-A, VI-B, and VII-B as identified in Table 1 of § 176.170(c) of this chapter, and limited to conditions of use B through H described in Table 2 of § 176.170(c) of this chapter, or foods of types III, IV-A, V, VI-C, and VII-A as identified in Table 1 of § 176.170(c) of this chapter and limited to conditions of use C through G described in Table 2 of § 176.170(c) of this chapter.

[46 FR 59236, Dec. 4, 1981, as amended at 52 FR 30920, Aug. 18, 1987; 53 FR 30049, Aug. 10, 1988; 54 FR 12432, Mar. 27, 1989; 54 FR 14734, Apr. 12, 1989; 55 FR 52990, Dec. 26, 1990; 56 FR 1085, Jan. 11, 1991; 59 FR 13650, Mar. 23, 1994; 59 FR 25323, May 16, 1994; 61 FR 33847, July 1, 1996; 61 FR 51588, Oct. 3, 1996; 61 FR 65943, Dec. 16, 1996; 63 FR 56789, Oct. 23, 1998; 63 FR 68392, Dec. 11, 1998; 64 FR 26843, May 18, 1999; 65 FR 16316, Mar. 28, 2000]

§ 178.3297 Colorants for polymers.

The substances listed in paragraph (e) of this section may be safely used as colorants in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions and definitions set forth in this section:

(a) The term *colorant* means a dye, pigment, or other substance that is used to impart color to or to alter the color of a food-contact material, but that does not migrate to food in amounts that will contribute to that food any color apparent to the naked eye. For the purpose of this section, the term “colorant” includes substances such as optical brighteners and fluorescent whiteners, which may not themselves be colored, but whose use is intended to affect the color of a food-contact material.

(b) The colorant must be used in accordance with current good manufacturing practice, including use levels which are not in excess of those reasonably required to accomplish the intended coloring effect.

(c) Colorants in this section must conform to the description and specifications indicated. If a polymer described in this section is itself the subject of a regulation promulgated under section 409 of the Federal Food, Drug, and Cosmetic Act, it shall also comply with any specifications and limitations prescribed by that regulation. Extraction testing guidelines to conduct studies for additional uses of colorants under this section are available from the Food and Drug Administration free of charge from the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, 240-402-1200